MÖLNLYCKE HEALTH CARE

K112257

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 20 2011

Biogel® PI OrthoPro® Brown Surgical Glove

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: August 4, 2011

Applicant:
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
Registration number: 3004763499
Owner/Operator Number: 8030877

Official Correspondent:
Angela L. Bunn, RAC
Director, Regulatory Affairs for the Americas
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e-mail: angela.bunn@molnlycke.com

Trade/Proprietary Name: Biogel® PI OrthoPro® Brown Surgical Glove

Common Name: Surgeon's Glove

Classification Name: Surgeon's Glove

Device Class: Class 1

Regulation Number: 21 CFR 878.4460

Product Code: KGO

Predicate Device Name(s): Poly-isoprene Non-Latex Sterile Powder-Free Surgeon's Glove (K050184)

Description of Device:

The proposed device, the Biogel® PI OrthoPro® Brown Surgical Glove is manufactured of non-latex (polyisoprene) colored with brown pigmentation. The Biogel® PI OrthoPro® Brown Surgical Glove is manufactured of the exact same material and coated with the Biogel® Coating which is used on the currently cleared device(s) that have been legally marketed by Mölnlycke Health Care for many years. The differences in the proposed glove and the predicate are as follows:

- Addition of a Brown Colorant
- Thicker Glove
- New Former

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The glove former design used in the manufacture of this glove allows the Biogel® PI OrthoPro® Brown Surgical Glove to provide the user with this additional feature:

- Slightly Curved Former with Independent/Displaced thumb

Intended Use/Indication for Use:

The Biogel® PI OrthoPro® Brown Surgical Glove is a disposable device made of non-latex (polyisoprene) colored brown, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

Technological Characteristics:

The Biogel® PI OrthoPro® Brown Surgical Glove is substantially equivalent to the Poly-isoprene Non-Latex Sterile Powder-Free Surgeon's Glove (K050184). All of the assessed devices have similar indications for use, materials, product design, labeling claims and method of operation.

The difference in the proposed device, Biogel® PI OrthoPro® Brown Surgical Glove is the thickness, a slight change to the former and the addition of the brown colorant.

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Table 1-A below provides a clear detailed comparison of the proposed device (Biogel® PI OrthoPro® Brown Surgical Glove) when compared to the predicate device.

Table 1-A Substantial Equivalence Comparison Table of Product Features		
Feature	**Biogel® PI OrthoPro® Brown Surgical Glove Proposed Device**	**Poly-Isoprene Non-Latex Sterile Powder-Free Surgeon's Glove Predicate Device**
510(k) Clearance	TBD	K050184
Manufacturer	Mölnlycke	Mölnlycke
Common Name	Surgeon's Glove	Surgeon's Glove
Classification #	Class I	Class I
Classification Name	21 CFR 878.4460	21 CFR 878.4460
Product Code	KGO	KGO
Indication For Use/Intended Use	The Biogel® PI OrthoPro® Brown Surgical Glove is a disposable device made of non-latex (polyisoprene) that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.	Poly-Isoprene non-latex sterile powder-free surgeon's glove is disposable device made of Poly-Isoprene that is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious material and other contaminants.
Materials	Polyisoprene	Polyisoprene
Coated	Yes	Yes
Powder Free	Yes	Yes
Colored	Brown	Natural
Sterilization Method and Sterility Assurance Level (SAL)	Radiation 10^{-6} SAL	Radiation 10^{-6} SAL
Biocompatibility	Materials have been assessed based to ISO 10993	Materials have been assessed based to ISO 10993

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Performance Testing:

Test	Result
Primary Skin Irritation	Gloves are non-irritating.
ISO Closed Patch Sensitization	Gloves do not display any potential for sensitization.
Dimensions	Gloves meet requirements of ASTM D3577.
Physical Properties	Gloves meet requirements for rubber surgical gloves per ASTM D3577.
Freedom from Holes	Gloves exceed the requirements of 21 CFR 800.20 and ASTM D3577.
Powder Residual	Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577 testing using ASTM standard D6142, Standard Test Method for Residual Powder on Medical Gloves. Results generated values below 2mg of residual powder per glove.

Clinical Testing:

No clinical data was required.

Conclusion:

The Biogel® PI OrthoPro® Brown Surgical Glove met the technological and performance characteristics of ASTM D3577 and are substantially equivalent to predicate device indentified in this summary with respect to intended use, materials, and design.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Angela L. Bunn
Director, Regulatory Affairs for the Americas
Molnlycke Health Care US, LLC
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SEP 20 2011

Re: K112257
Trade/Device Name: Biogel® PI OrthoPro® Brown Surgical Glove, Powder-Free, Sterile
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 25, 2011
Received: August 26, 2011

Dear Ms.Bunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: **Biogel® PI OrthoPro® Brown Surgical Glove, Powder-Free, Sterile**

Indications For Use:

The Biogel® PI OrthoPro® Brown Surgical Glove is a disposable device made of non-latex (polyisoprene) colored brown, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants.

Prescription Use _____ AND/OR Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Claire-Wilkins

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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